REMARKS/ARGUMENTS

Claims 21 to 28 and 30 to 32 are pending in the current application. Claims 21, 31 and 32 are amended, without prejudice. Claims 1 to 20 and 29 are cancelled, without prejudice. New claim 33 has been added. No new matter has been added. Support for the new claim can be found in the specification, and in particular at page 28, paragraphs 1 to 3 and page 29, paragraphs 1 to 2.

In view of the foregoing amendments and the following remarks, reconsideration and withdrawal of the objections and rejections are respectfully requested. Applicants reserve the right to pursue subject matter that remains after the prosecution of the present application in a future continuing patent application, for example, a division.

Discussion of the Rejections under 35 U.S.C. § 112

Claim 29 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for preventing diseases. Claim 29 is also rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description with regard to "the nexus between the modulation of the β2-adrenoreceptor and a useful treatment of a disease/condition". Claim 29 is further rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for treating all diseases modulated by the β2-adrenoreceptor. Although applicants respectfully disagree, claim 29 has been cancelled.

Claims 21, 31 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for making solvates of the claimed compounds. Although applicants respectfully disagree, claims 21, 31 and 32 have been amended to delete the term "solvates".

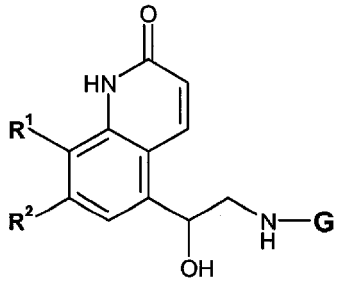
Discussion of the Rejections under 35 U.S.C. § 102

Claims 21 to 32 are rejected under 35 U.S.C. §§ 102(b) and 102(e) as allegedly anticipated by U.S. Patent No. 6,800,643 to Cuenoud ("Cuenoud"), which is the US National Phase of WO2002/045703 (also cited), U.S. Patent No. 6,878,721 to Cuenoud et al. ("Cuenoud 2"), which is the US National Phase of WO2000/075114 (also cited), or U.S. Patent No. 7,008,951 to Cuenoud et al. ("Cuenoud 3"). Claims 21 to 32 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 7,250,426 to Konetzki et al. ("Konetzki"), U.S. Patent No. 7,417,051 to Banholzer et al. ("Banholzer"), U.S. Patent No. 7,317,102 to Mammen et al. ("Mammen") and U.S. Patent No. 7,534,890 to Lohse et al. ("Lohse"). Applicants respectfully traverse these rejections because each of the cited references does not disclose each and every element of applicants' claimed inventions.

For a reference to anticipate a claim under 35 U.S.C. § 102, "the identical invention must be shown in as complete detail as is contained in the ... claim" (*Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989)). Further, "a claim is anticipated only if each and

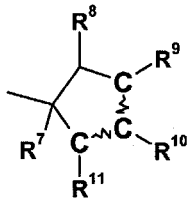
every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" (*Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic (*In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)). In particular, the examiner must provide a basis in fact and/or technical reasoning to reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (*Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)).

Applicants claims define a compound of formula I



I

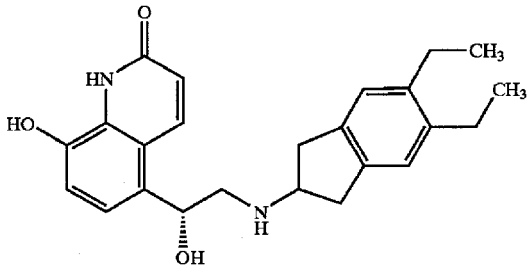
in free or salt or solvate form, where R^1 is hydroxy and R^2 is hydrogen; G is a group having the formula Ib:



Ib

C~C denotes C=C or CH-CH; R^7 and R^8 are both hydrogen; R^9 and R^{10} are independently selected from the group consisting of hydrogen and C_1-C_{10} alkyl, or R^9 and R^{10} together form a C_3-C_{10} cycloalkyl or C_3-C_{10} cycloalkenyl, and in either case wherein R^9 and R^{10} are optionally substituted by C_1-C_{10} alkyl; and R^{11} is a C_3-C_{15} carbocyclic group or C_1-C_{10} alkyl substituted by a C_3-C_{15} carbocyclic group (*see, e.g.*, claim 1).

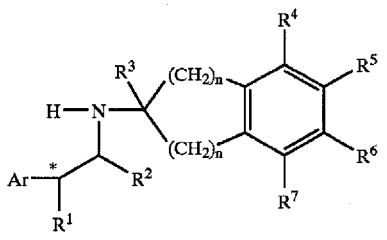
Cuenoud and Cuenoud 3 disclose the compound



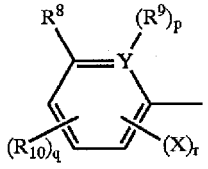
(*see, e.g.*, Cuenoud at Col. 1, lines 8 to 25; Cuenoud 3 at Col. 1, lines 15 to 32). Thus, at least one difference between the claimed invention and Cuenoud/Cuenoud 3 is that the claimed

invention has an R^{11} C_3-C_{15} carbocyclic group or C_1-C_{10} alkyl substituted by a C_3-C_{15} carbocyclic group whereas Cuenoud/Cuenoud 3 has a hydrogen. Cuenoud/Cuenoud 3 does not provide any reason or suggestion that would motivate one of ordinary skill in the art to modify Cuenoud/Cuenoud 3 in such a way as to obtain the presently claimed compounds.

Cuenoud 2 discloses a compound of formula



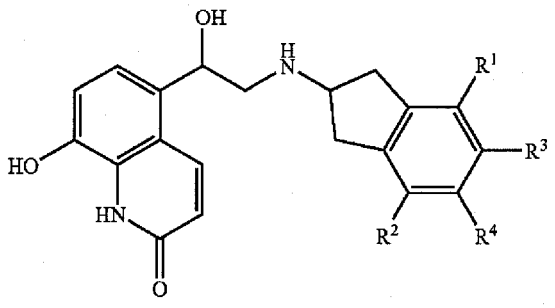
where Ar is a group of formula



wherein, in relevant part, R^4, R^5, R^6 and R^7 are each independently hydrogen, halogen, cyano, hydroxy, alkoxy, aryl, alkyl, alkyl substituted by one or more halogen atoms or one or more hydroxyl or alkoxy groups, alkyl interrupted by one or more hetero atoms, alkenyl, trialkylsilyl, carboxy, alkoxycarbonyl, or $-CONR^{11}R^{12}$ where R^{11} and R^{12} are each independently hydrogen or alkyl, or R^4 and R^5, R^5 and R^6 or R^6 and R^7 together with the carbon atoms to which they are attached denote a carbocyclic or heterocyclic ring, X is halogen or halomethyl or alkyl and R^8 is $-NHR^{18}$ where $-NHR^{18}$ and R^9, together with the carbon atoms to which they are attached, denote a 5- or 6-membered heterocyclic (*see, e.g.*, Cuenoud 2 at Col. 1, lines 1 to 67).

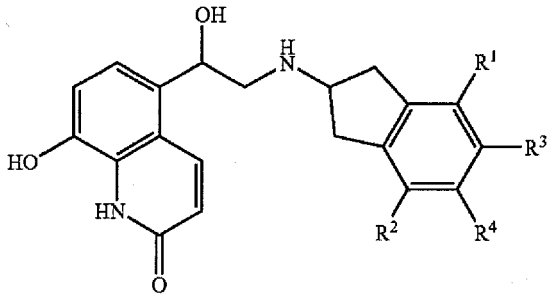
Thus, at least three differences between the claimed invention and Cuenoud 2 is that (a) the claimed invention has an R^{11} C_3-C_{15} carbocyclic group or C_1-C_{10} alkyl substituted by a C_3-C_{15} carbocyclic group whereas Cuenoud 2 has an unsubstituted non-cyclic group or joins with an additional ring substituent to form a carbocyclic ring, (b) the claimed invention has a =O substituent whereas Cuenoud has hydrogens (i.e., no substituents) on the heterocyclic formed by $-NHR^{18}$ and R^9, and (c) the claimed invention has a hydrogen whereas Cuenoud 2 at X has a halogen, halomethyl or alkyl. Cuenoud 2 does not provide any reason or suggestion that would motivate one of ordinary skill in the art to modify Cuenoud 2 in such a way as to obtain the presently claimed compounds.

Konetzki discloses a compound of formula 2'



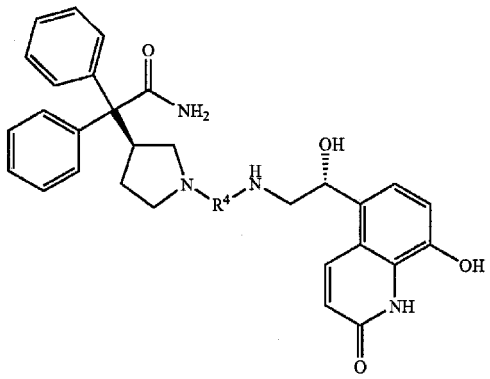
wherein, in relevant part, R^1 and R^2 are hydrogen or C_1-C_4 alkyl; and R^3 and R^4 are hydrogen, C_1-C_4alkyl, -O C_1-C_4alkyl, C_1-C_4alkylene-O-C_1-C_4alkyl or together are C_1-C_4alkylene or –O C_1-C_4-alkylene-O- (*see, e.g.*, Konetzki at Col. 2, lines 45 to 67 and Col. 3, lines 1 to 15). Thus, at least one difference between the claimed invention and Konetzki is that the claimed invention has an R^{11} C_3-C_{15} carbocyclic group or C_1-C_{10} alkyl substituted by a C_3-C_{15} carbocyclic group whereas Konetzki has a hydrogen or an unsubstituted C_1-C_4 alkyl. Konetzki does not provide any reason or suggestion that would motivate one of ordinary skill in the art to modify Konetzki in such a way as to obtain the presently claimed compounds.

Banholzer discloses a compound of formula 2a'



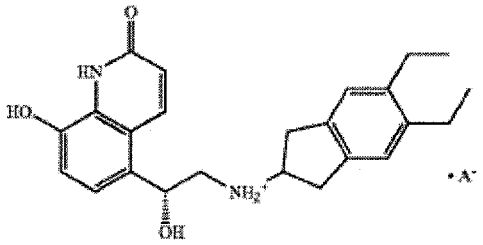
wherein, in relevant part, R^1 and R^2 are hydrogen or C_1-C_4 alkyl; and R^3 and R^4 are hydrogen, C_1-C_4alkyl, -O C_1-C_4alkyl, C_1-C_4alkylene-O-C_1-C_4alkyl or together are C_1-C_4alkylene or –O C_1-C_4-alkylene-O- (*see, e.g.*, Banholzer at Col. 3, lines 40 to 65). Thus, at least one difference between the claimed invention and Banholzer is that the claimed invention has an R^{11} C_3-C_{15} carbocyclic group or C_1-C_{10} alkyl substituted by a C_3-C_{15} carbocyclic group whereas Banholzer has a hydrogen or an unsubstituted C_1-C_4 alkyl. Banholzer does not provide any reason or suggestion that would motivate one of ordinary skill in the art to modify Banholzer in such a way as to obtain the presently claimed compounds.

Mammen discloses a compound of formula IIIa



wherein R^4 is defined as various compounds in Table I, such as $-(CH_2)_7-$ or cyclopentyl (*see, e.g.*, Mammen at Col. 23, lines 15 to 65, Col. 24 lines 1 to 65, Col. 25, lines 1 to 30). Thus, at least one difference between the claimed invention and Mammen is that the claimed invention has an NH group binding directly to the ring carbon of a substituted cyclopentyl whereas Mammen has an NH group binding to an R4 group, said R4 group binding directly to the ring nitrogen of a substituted azolidine. Mammen does not provide any reason or suggestion that would motivate one of ordinary skill in the art to modify Mammen in such a way as to obtain the presently claimed compounds.

Lohse discloses a compound of formula IV



wherein A- is an anion (*see, e.g.*, Lohse at Col. 7, lines 25 to 35). Thus, at least one difference between the claimed invention and Lohse is that the claimed invention has an R^{11} C_3-C_{15} carbocyclic group or C_1-C_{10} alkyl substituted by a C_3-C_{15} carbocyclic group whereas Lohse has a hydrogen. Lohse does not provide any reason or suggestion that would motivate one of ordinary skill in the art to modify Lohse in such a way as to obtain the presently claimed compounds.

The Action also does not identify any reason why the skilled artisan would have been motivated to modify Cuenoud, Cuenoud 2, Cuenoud 3, Konetzki, Banholzer, Mammen, or Lohse to obtain the presently claimed invention. This, however, falls far short of providing the requisite motivation because it has not been shown why one of ordinary skill in the art would modify each differing substituent so as to obtain the presently claimed compounds. Indeed, the Patent Office has the burden of presenting factual evidence that would indicate that the claimed compounds are prima facie obvious (*In re Lunsford*, 148 U.S.P.Q. 721 (C.C.P.A. 1966). In the absence of such a showing, such a rejection is based upon impermissible hindsight (*In re Fritch*, 23

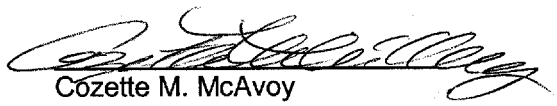
U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992) ("it is impermissible for an Examiner, in proffering a 35 U.S.C. § 103 rejection, to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art to render the claimed invention obvious")). Accordingly, reconsideration and withdrawal of the above rejections are requested respectfully for at least this reason.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. If there are any issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney.

It is hereby requested that the term to respond to the Action of July 24, 2009 be extended pursuant to 37 C.F.R. § 1.136(a) for three (3) months, from October 24, 2009 to January 25, 2010 (January 24, 2010 is a Sunday). The Commissioner is hereby authorized to charge any fees required to Deposit Account No. **19-0134** in the name of Novartis.

Respectfully submitted,



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